National Institutes of Health

Deputy Ethics Counselors / Ethics Coordinators
Minutes: April 13, 2004
Bldg 31, Conference Room 6, 1:30 pm

1. **OIG Inspection at NIH**

MaryJane Meyers of the NIH Office of Management Assessment explained OMA's role in OIG (and other outside, e.g., GAO) investigations:

- Function as liaison between the OIG, GAO and other entities to the NIH office(s) affected by the investigation;
- Ensure that the investigators talk to the correct NIH staff and get appropriate information in a timely manner;
- Review draft reports and ensure that the appropriate NIH staff review the draft report and provide comments in a timely manner to be incorporated into the final report.

Ms. Meyers introduced staff from the HHS Office of the Inspector General: Sara Schulman (Boston Office), Aimee Golbitz (Central Office), and Tanaz Dutia. (Philadelphia Office). Ms. Schulman explained the role of the IG and the current OIG investigation at the NIH. The OIG is an independent office within HHS whose purpose is to ensure program integrity. They are not auditors and do not review specific actions but rather look at systems. The goals of the current study on conflict of interests at the NIH include three types, **covering all 278 filers as of February 2004**:

- Descriptive: review all outside activities and describe them generally using descriptive statistics (trends, number of each type of activity, amount of time, etc).
- Compliance: review forms for compliance with requirements, e.g., appropriate forms submitted, adequate information on which to base a decision, etc.
- Process: review specific processes within the IC and NIH Ethics Office for how 520 requests are handled, from first questions through review, approval/disapproval, and informing employee of the decision.

Note: Senior NIH officials includes those for whom the NIH DEC is their DEC, e.g., IC Directors, Deputy Directors, Clinical Directors, Scientific Directors, and OD Office and Associate Directors.

OIG staff will talk with each IC ethics staff separately. This is not a repeat of the recent OGE review; it covers all ICs, it is specific to outside activities, and the audience for the report is different. OIG staff will then prepare a draft report which comes to the NIH for review and comments. Final report will include those comments and is publicly released. They hope to obtain a final list of employees whose DEC is the NIH DEC within the next couple of weeks, and contact IC ethics staff shortly thereafter for appointments, probably in June. They will also review the report of the NIH Blue Ribbon Panel on Conflict of Interests.

ACTION: DECs/ECs will reply as soon as possible to Ms. Jaffe's request for confirmation of the individuals who are under the jurisdiction of the NIH DEC.

Note: NIH and OGC Ethics Division staff are also reviewing other positions that may be considered equivalent to SES, e.g., Extramural Program Directors who report directly to the IC Director. It is anticipated that the HHS Designated Agency Ethics Official (DAEO) will request an equivalency determination from OGE which would then require these individuals to file public financial disclosure reports. These "potential public filers" are NOT covered by the current IG investigation.

2. **NIAMS Employee Tracking System**

Mr. Danny Heise of NIAMS gave a demonstration on the NIAMS Employee Tracking System. This is a web-based system internal to NIAMS which was developed to track and orient new employees. It provides an orientation to all new employees. When information on a new employee is added, the system generates a report/checklist to ensure all necessary actions and orientations are accomplished. It also sends emails to appropriate individuals to permit them to quickly know about departing and new employees. The system also includes non-FTE individuals, e.g., contract employees. The code (IIS and ASP) can be exported to any other IC.

ACTION: Any interested IC can contact Mr. Heise in NIAMS for assistance in exporting the code.

3. **Travel Issues and Official Duty Activity Approval**

Ms. Jaffe met with Ken Stith, Joel Papier, and Janet Dudrick of the NIH Office of Management regarding Dr. Zerhouni's memo of November 3, 2003, on the topic of travel approval. The issue now is approval of the official duty activity prior to initiation of the travel order, and who gives that approval. The following criteria were suggested:

- For official travel (TDY - Temporary Duty): An Official Duty Activity (ODA) request is submitted for the activity. Following approval by NIH DEC, travel approval is initiated.
  - For IC Directors & OD Associate & Office Directors: Dr. Kington signs ODA request both as supervisor and DEC. Then travel approval is initiated.
  - For the IC DD, SD, and CD: The IC Director signs the ODA request as supervisor. Dr. Kington signs as DEC, and then travel approval is initiated.

- For local travel with a non-governmental entity, under consideration for the "Top 5" is a 'calendar approach', e.g., send a weekly calendar showing local activities with non-governmental entities. Calendars would be submitted weekly to Dr. Kington, with a cc to the NIH Ethics Office for inclusion in the employee's ethics file. Electronic submission would be permissible. It is up to the individual whether to claim local travel expenses. Until a decision is made, these individuals will continue to obtain advance approval for all travel, including local travel.

- For local travel with government entities, no ODA approval is necessary. It is up to the individual whether to claim local travel expenses.

Note: Top 5 includes: IC Directors, IC Deputy Directors, IC Scientific Directors, IC Clinical Directors, OD Associate and Office Directors

The attendees discussed issues associated with whether the IC DEC/EC would be involved in this process, e.g., would it create additional burden for the IC ethics staff, would it create a 'shadow' file which must be maintained per NARA requirements, or would the IC DEC/EC prefer to be involved on behalf of their employees. The attendees decided that the IC DEC/EC would continue to be involved in all ethics requests for this group of employees, and would therefore forward the request to the NIH Ethics Office and keep track of the request for the employee, as is currently done for outside activity requests. This provides for a single procedure for all ethics requests for these individuals, e.g.:

- Employee (or IC ethics staff) produce the appropriate form for the request
- IC ethics staff review and ensure completeness and compliance with requirements
- NIH Ethics Office staff review and ensure completeness and compliance with requirements
- Review/decision by NIH DEC
- Copy returned to IC ethics staff for distribution to employee

ACTION: Ms. Jaffe will draft a policy memo for review and eventual inclusion on the NIH Ethics Program web site.

4. **Continuing Consulting with Law Firm (Outside Activity)**
Discussion centered on whether employees should be given permission to engage in an continuing arrangement with a law firm or whether approval should be sought for each case on which the employee would consult. It was noted that frequently there is no 'case' until after significant consultation, e.g., the attorney needs to determine whether a viable case exists based on the consultation with the expert. The ICs do not all approve activities the same.

For clarification, the following explanations/definitions are provided:

- **Expert testimony** is a short-hand term for "service as an expert witness," the terminology used in the Standards (5 CFR 2635.805). The term is broad enough to cover providing a written report (especially where that report, by rule or custom, will be shared with opposing counsel), appearing for a deposition, or otherwise providing information or testimony under oath, when the employee is not a fact witness.

- **Consulting with a law firm** is a fairly preliminary activity, and should not involve written reports or opinions. Law firms often consult as they formulate their theory of a case, identify issues, etc. These consultations are typically verbal, although the physician or other professional may have reviewed paper records before having the discussion with the attorney.

Following discussion, the following conclusions were reached by the attendees. There are three (3) circumstances when an HHS 520 package is required and may be approved:

- The employee is invited to consult with a law firm (as distinguished from serving as an expert witness) in relation to a particular set of facts (e.g., a current or potential case).

- The employee is invited to serve as an expert witness in relation to a particular pending case or lawsuit (which includes consultative review of the particular case). If it is known that service as an expert witness will be required, this must be clearly stated in the HHS 520 submission package.

- The employee was originally invited to consult on a particular set of facts and is subsequently asked to serve as an expert witness in relation to a lawsuit or case arising from those facts.

Note: Approvals should always be limited to particular sets of facts or lawsuits/cases; law firm activities for which continuing approval have been granted in the past increase the potential that an employee may inadvertently consult or testify on a subject matter related to his/her official duty, or otherwise violate existing statute, regulation or policy.

ACTION ITEMS:

1. Ms. Jaffe will provide a draft policy for inclusion in the outside activities manual chapter.
2. Ms. Jaffe will revise the NIH 2657 Part C regarding expert witness issues, e.g., approval is for general consulting only (to be distributed for review with new outside activities manual chapter).
3. Ms. Weaver will share the summary document electronically.
4. Ms. Jaffe will have the summary document added to the NIH Ethics Program website.

5. **NIH Ethics Advisory Committee (NEAC):** In reviewing requests, NEAC members look at the employee's responsibilities beyond the science in which they are involved officially. They consider business aspects of their official duties too, including whether they are involved in procurement and whether the outside organization sells to the IC. They also consider whether the recusal requirement associated with an outside activity will negatively affect the employee's official responsibilities and if yes, is resolution possible via an authorization or waiver. Several issues regarding NEAC policies and the process were discussed:

- **Expedited Review:** NEAC initiated a process whereby requests to engage the following activities are considered "presumed approved" and receive expedited review. NEAC members will discuss them only if there are issues with any particular request. These activities will receive expedited review and are presumed approved because they meet the regulatory requirements and Dr. Kington does not need NEAC review for such 'straight-forward' activities.

  - Private professional practice of less than 1000 hours/year or $150,000 or less per year.
  - Teaching, including teaching related to official duties, are specifically addressed in the regulation.

  ACTION: Ms. Jaffe will distribute a draft policy for review, for eventual finalization and inclusion on the NIH Ethics Program web site.

- **Activities During Re-Submission Process:** Employees need to be reminded that they may not start an activity until they have received approval. They also may not attend meetings or in other ways participate in previously approved activities until the new approval is received. They do not need to resign their positions, but they cannot attend meetings or provide services until they receive approval from the NIH DEC. Without that approval, they may have to return any income they received during the non-approved time.

- **What to Submit in 520 Request Packages:** Many positions do not have a position description or written duties, especially intramural scientists. Some intramural scientists have descriptions of their research termed a "Z0.1" When available, include the Z01.

- **Follow Up With Employees:** In the past, when the NIH Ethics Office staff needed additional information, they contacted the employees directly. Many IC ethics staff requested to be cc'd on the messages so they could remain aware of the issues and the progress of the review.

  ACTION: NIH Ethics Office staff will cc the IC Ethics Coordinator when additional information is requested from employees for requests going to NEAC.

- **Responses on Forms:** There continues to be insufficient explanations on the unnumbered supplemental form, especially question #3, for why and how the requested activity is not related to the employees current official duties. NEAC members have indicated that this question in particular must be answered appropriately to permit an adequate and accurate review of the request. DEC/EC attendees requested some examples to help employees complete the requests.

  ACTION: Examples will be provided in the revised manual chapter on outside activities, which will be ready for review shortly after the report of the NIH Blue Ribbon Panel on Conflict of Interest is released. In the interim, examples will be added to the NIH Ethics Program web site in a link from the forms page.

6. Timelines of Current Conflict of Interest Issues at the NIH:

- Blue Ribbon Panel on Conflict of Interests - next meeting is May 6th. A report is expected shortly thereafter.
- The House Energy/Commerce Oversight Committee (Chairman Greenwood) is expected to hear NIH testimony on May 12th.

Next DEC/EC Meeting: Tuesday, May 11, 2004, 1:30 pm
Bldg 31, C Wing, 6th floor, Conference Room 6